REMARKS

Claims 1-10 are pending in the present application. Claims 4-6 are withdrawn from consideration. Claims 1-3 and 7-10 stand rejected. No new matter is added.

Election and Restriction

The Examiners indicates that based on a telephone conversation made with MaryAnne Armstrong, Applicant's representative, on November 27, 2006, the claims are interpreted based on a two-part dosing regime. In addition, the claims of the instant application are interpreted as they relate to arthritis, based on a previous election.

Information Disclosure Statement

The Examiner acknowledges the receipt of the Information Disclosure Statement filed on August 15, 2006 and its re-submission on September 25, 2006. The Examiner notes the Applicants reliance on the same references cited on the accompanying form 1449 filed with parent application; however, the Examiner has failed to consider these references and alleges that a legible copy of each reference was not submitted with the parent. The Applicants submit that all non-patent and foreign references cited on the IDS of September 25, 2006 were submitted electronically in co-pending application 10/145,992 and received by the USPTO to the parent file on January 23, 2007 and should be available to the Examiner from the co-pending application. However, the Applicants intend to re-submit these references either electronically or by hardcopy to the file under a separate cover. In addition, the Applicants submit herewith an additional Information Disclosure Statement under 37 C.F.R. 1.97(c) with a form 1449 and all references included in that form 1449 electronically.

Specification

The Examiner invites the Applicants to update the claim to priority of the instant application through an amendment to the specification, which is made herein. The Examiner also invites the Applicants to update the title and abstract of the present application to relate to the claims by amendment. The Applicants amend the title herein and provide a new abstract. The Examiner also notes that all trademarks should be capitalized and accompanied by the ™ or ® symbol. The Applicants amend the specification herein to include a trademark symbol at paragraph 0069 for the term SEPHAROSE® and ENHANCE™. Finally, the Examiner refers to the guidelines for the preferred layout of a patent

application and suggests that the Applicants use these guidelines. The Applicants respectfully note that the guidelines provided by the Examiner are merely guidelines for the arrangement of the specification and are not required for the examination and issue of a patent. Therefore, the Applicants do not find it necessary to amend the specification for this purpose.

Interference Estoppel

Claims 1-3 and 7-10 stand rejected based on the Interference Estoppel Rule 1.658(c) for failure to take action during Interference 102,572. The Examiner alleges that the Applicant's rights to claims 1-3 and 7-10 could have been raised during the interference 102,572 or an additional interference, and they are now estopped from pursuing this subject matter. The Applicants respectfully submit that Rule 1. 658(c) has been removed from the Code of Federal Regulations in 2004, making rejection under this provision moot. However, for the purpose of clarity, the Applicants wish to note the MPEP § 2308.03 *Estoppel Within the Office Interference Proceedings*, which refers to new rule 37 C.F.R. § 41.127 and which states two main types of interference estoppel as follows:

> First, a losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); Ex parte Tytgat, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). Second, a losing party is procedurally barred from seeking from the examiner relief that could have been--but was not--sought in the interference. 37 CFR 41.127(a)(1); Ex parte Kimura, 55 USPQ2d 1537 (Bd. Pat. App. & Inter. 2000)

The Examiner alleges that if claims 1-3 and 7-10 define an invention which is not separately patentable from the subject matter of the lost count, then the Applicants are barred from filing this application based on *In re Deckler*. The Examiner further alleges that if the Applicants assert that the subject matter of claims 1-3 and 7-10 is not the same patentable invention as the lost Count then the Applicants are not entitled to the claims based on their failure to move to put the subject matter in the interference.

The Applicants respectfully disagree with the Examiner's interpretation of Interference Estoppel. First, the Applicants note that the Examples in MPEP § 2308.03 provide that if the claims filed in a continuation application are deemed by the Examiner to be obvious in light of the subject matter of the lost count, then the Examiner has the burden of showing that newly claimed subject matter would be obvious in light of the lost count. The Applicants respectfully submit that the Examiner has not met this burden in this case, as he has made no showing as to how the newly claimed subject matter would be

obvious in view of the lost count. Thus, interference estoppel does not apply to the present claims. Second, the Applicants respectfully submit that a procedural bar of the new claims should only apply if the new claims would be obvious in view of a count of the interference. The rules do not require that procedural estoppel apply to all patentable subject matter submitted in a continuation, only subject matter that could have been part of the interference. Because the Examiner has not shown or even asserted that the new claims would be obvious in view of the counts of the interference, it is improper for him to assume that they could have been part of the interference. Furthermore, the Applicants respectfully submit that there is no disclosure in the '611 specification or '415 patent that is directed to a multiple part treatment regime, particularly for arthritis. Therefore, the Applicants could not have properly requested an interference between the instant claims and the '611 specification. Thus, procedural estoppel does not apply to the present claims.

35 U.S.C. § 102(b)

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Adair, *et al.* (EP 0388 151 A1). The Examiner alleges that Adair, *et al.* teach methods of providing modified antibodies for diagnostic and therapeutic procedures. The Applicants respectfully traverse this rejection. A single prior art reference anticipates a claimed invention only if it identically shows every element of the claimed invention. *In re Bond,* 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). The Applicants respectfully submit that the claims of the present invention are directed to methods of treating a human patient comprising repeated administration of a therapeutically effective amount of an antibody. The Applicants further submit that Adair, *et al.* do not disclose repeated treatment with an antibody, thus, Adair, *et al.* do not teach each and every element of the claimed invention.

Applicants respectfully submit that, in view of the forgoing remarks, the Applicants have overcome the rejection of claims 1 and 2 under 35 U.S.C. § 102(b). Accordingly, the Applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 103(a)

Claims 1, 2, 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Adair, *et al.* in view of Queen, *et al.,* U.S. Patent No. 5,530,101 or Waldman *et al.*, U.S. Patent No. 5,846,534. Specifically, the Examiner alleges that Adair, *et al.* teach methods of providing glycosylated antibodies and also the advantages of modifying the glycosylation of such antibodies as it applies to activating complement. The Examiner concedes that Adair, *et al.* differs from the instant claims in that Adair, *et al.*

does not disclose the elected invention of treating arthritis. The Examiner goes on to allege that Queen, *et al.*, teach methods for reducing immunogenicity to antibodies and also single and multiple administration depending on the severity of the disease. Finally, the Examiner refers to Waldman, *et al.* as teaching recombinant antibodies to treat autoimmune disease.

The Applicants respectfully traverse this rejection. The Examiner uses hindsight reconstruction by taking individual elements from each reference (none of which disclose arthritis) and assumes that a skilled artisan at the time the invention was made would have known to use a multiple dose treatment regimen with glycosylated IgG for arthritic disease. The Applicants submit the following article: Parekh, *et al. Nature* 316:452-457 (1985), submitted herewith for the Examiner's convenience. Parehk, *et al.* demonstrate that in patient populations of patients having arthritide diseases, such as rheumatoid arthritis or osteoarthritis, IgG molecules of these patients contain truncated glycan chains compared with normal individuals. Thus, Parehk, *et al.* suggest that these two disease may be "glycosylation diseases." Parehk, *et al.* further suggest that oligosaccharides terminating in N-acetylglucosamine (i.e., having a truncated glycan adduct) could create new protein oligosaccharides that may be immunogenic, increase the population of certain IgG subpopulations raising immunogencity to these IgG, or could effectively make the IgG sticky creating an autoaggregation rather than an immune response. Therefore, Parehk, *et al.* suggest that aberrantly glycosylated IgG might be immunogenic in patients already having arthritic disease. The Applicants, therefore, submit that multiple administration of a glycosylated IgG for the treatment of a disease such as arthritis, at the time the invention was made, might be expected to increase immunogenicity to the IgG. Therefore, a skilled artisan would not be motivated to treat a disease such as arthritis with a glycosylated IgG and particularly with a multiple dose treatment regimen.

The Applicants respectfully point out that proper glycosylation of the Fc region, as described by Adair, *et al,.* is necessary to induce complement. However, Adair, *et al.* do not teach that a glycosylated antibody could be used for the treatment of arthritis or any "glycosylation diseases" as described by Parehk, *et al.* Similarly, Queen, *et al.* is directed to the functional characteristics of a humanized IgG and does not suggest the treatment of arthritis by a multiple-dose regimen. Queen, *et al.* suggest reducing immunogenicity by a human to a chimeric antibody by "humanizing" the antibody (i.e., altering an antibody comprising rodent CDRs and human frameworks with mutations necessary to preserve antigen binding). Thus, any multiple dose therapy suggested by Queen, *et al.* is based on the assumption that immunogenicity to a humanized antibody is reduced because it contains fewer foreign sequences in its framework region compared with rodent framework. They make no reference to glycosylation. Finally, Waldman, *et al.* may suggest that CAMPATH-1 be administered for autoimmune disease, but they do not

suggest that it be used for arthritis. Given the discussion of Parehk. *et al.* above, it is unlikely that the skilled artisan at the time the invention was made would have considered using glycosylated IgG for the treatment of arthritis in a multiple dose regimen. Thus, the Applicants submit that although Waldman, *et al.* teach using CAMPATH-1 for autoimmune disease it is improper to assume that the skilled artisan would find obvious that all autoimmune disease be treated with multiple doses of glycosylated IgG, based on the findings of Parehk. *et al.* Therefore, the Applicants submit that it would not have been obvious to the skilled artisan at the time the invention was made to combine any of these references for a multiple dose treatment of arthritis with a glycosylated IgG.

Applicants respectfully submit that, in view of the forgoing remarks, the Applicants have overcome the rejection of claims 1, 2, 7-10 under 35 U.S.C. § 103. Accordingly, the Applicants respectfully request withdrawal of these rejections.

Obvious-type double-patenting

Claims 1, 2 and 7-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 21-28, 39 and 40 of co-pending application USSN 10/145,992 in view of Mather, *et al.* (U.S. Pat. No. 5,122,469), Zettlemeissl, *et al.* (Biotechnology 5:720-725(1987)), Handa-Corrigan, *et al.* (Enzyme Microb. Technol. 11:230-235 (1989)) and Schneider (J. Immunol. Methods 116:65-77 (1989)). The Examiner notes that given the species of autoimmune/arthritis in the instant application and the election of non-Hodgkin's lymphoma in the co-pending application, claims drawn to species disease of the instant application are not included in this provisional double patenting rejection. Should it be determined that a terminal disclaimer is necessary after allowable subject matter has been agreed, Applicants will timely file such disclaimer.

Conclusion

The Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the cancelled claims, the claims as originally filed, and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending claims is earnestly solicited. If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney.

Respectfully submitted,

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